

§ 482.92

facility, as requested by a patient or a dialysis facility.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery.* When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

(b) *Standard: Organ receipt.* After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.

(c) *Standard: Living donor transplantation.* If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

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§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waiting list management.* Transplant centers must keep their waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waiting list;

(ii) The center's decision not to place the patient on its waiting list; or

(iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

(i) Multidisciplinary patient care planning during the transplant period; and

(ii) Multidisciplinary discharge planning for post-transplant care.

(d) *Standard: Social services.* The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a